

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in this application.

Claims 1-14. (Canceled)

15. (Presently Amended) A composition comprising microcapsules comprising:
 - a. drug microparticles;
 - b. a first layer disposed over said microparticles, consisting essentially of ethylcellulose; and
 - c. a second layer disposed over said first layer, comprising an acrylic polymer, wherein said acrylic polymer is soluble in the stomach.
16. (Previously Presented) The microcapsules of claim 15, wherein the acrylic polymer comprises a cationic copolymer based on dimethylaminoethyl methacrylate and neutral methacrylic esters.
17. (Previously Presented) The microcapsules of claim 15, wherein the microcapsules comprise from 5% to 40% of the acrylic polymer relative to the total weight of the microcapsule.
18. (Previously Presented) The microcapsules of claim 15, wherein the microcapsules comprise from 10% to 25% of the acrylic polymer relative to the total weight of the microcapsule.
19. (Previously Presented) The microcapsules of claim 15, wherein the microcapsules have a drug to ethylcellulose weight ratio (phase ratio) of from 1:1 to 30:1.
20. (Previously Presented) The microcapsules of claim 15, wherein the microcapsules have a drug to ethylcellulose weight ratio (phase ratio) of from 3:1 to 15:1.

21. (Previously Presented) The microcapsules of claim 15, wherein the microcapsules have a median diameter of from 20 μm to 800 μm .
22. (Previously Presented) The microcapsules of claim 15, wherein the microcapsules have a median diameter of from 100 μm to 400 μm .
23. (Presently Amended) The microcapsules of claim 15, wherein the microcapsules have a drug potency of from 400 mg drug/g of microcapsules to 950 mg drug/g of microcapsules.
24. (Previously Presented) The microcapsules of claim 15, wherein the microparticles release 80% of the drug contained therein within 30 minutes in aqueous acidic media or simulated gastric fluid.
25. (Previously Presented) The microcapsules of claim 15, wherein said drug is selected from the group consisting of penicillins, cephalosporins, carbapenum, penems, penams, aminoglycosides, macrolides, ketolides, tetracyclines, and quinolones.
26. (Previously Presented) The microcapsules of claim 15, wherein said drug is selected from the group consisting of antibiotic agents, antibacterial agents; antiviral agents, analgesics, anesthetics, anorexics, antiarthritics, antiasthmatic agents, anticonvulsants, antidepressants, antidiabetic agents, antidiarrheals, antihistamines, anti-inflammatory agents, antiemetics, antineoplastics, antiparkinsonism drugs, antipruritics, antipsychotics, antipyretics, antispasmodics, H₂ antagonists, cardiovascular drugs, antiarrhythmics, antihypertensives, ACE inhibitors, diuretics, vasodilators, hormones, hypnotics, immunosuppressives, muscle relaxants, parasympatholytics, parasympathomimetics, psychostimulants, sedatives, antimigrane agents, antituberculosis agents, and tranquilizers.

27. (Previously Presented) The microcapsules of claim 15, formulated in a pharmaceutically administrable form.

28. (Previously Presented) The microcapsules of claim 27, wherein said pharmaceutically administrable form is selected from the group consisting of dry powders for extemporaneous suspensions, tablets, minitablets, capsules, monodose sachets, fast disintegrating tablets, and syrups.

29. (Withdrawn) A process for the production of the microcapsules of claim 15, comprising the following steps:

- i) coating drug microparticles with a first layer, comprising ethylcellulose; and
- ii) coating the product of step i) with a second layer, comprising an acrylic polymer.

30. (Withdrawn) The process of claim 29, wherein the first layer in step i) is applied by phase separation microencapsulation or by fluidized bed coating.

31. (Withdrawn) The process of claim 29, wherein the second layer in step ii) is applied by spraying a solution or suspension of acrylic polymer onto the coated microparticles obtained in step i), suspended in a fluidized bed.

32. (Withdrawn) The process of claim 31, wherein said solution or suspension comprises the following weight percentages of components, calculated with respect to the total weight of the solution:

- acrylic polymer: 4-20%
- alcohol: 30-94%
- water: 0-40%

- micronised inorganic material: 2-20%.

33. (Withdrawn) The process of claim 31, wherein said solution or suspension comprises the following weight percentages of components, calculated with respect to the total weight of the solution:

- acrylic polymer: 7-20%
- alcohol: 40-75%
- water: 10-35%
- micronised inorganic material: 5-9%.

34. (Withdrawn) The process of claim 32, wherein said alcohol is ethanol, and said micronised inorganic material is talc.

35. (Withdrawn) The process of claim 33, wherein said alcohol is ethanol, and said micronised inorganic material is talc.

36. (Withdrawn) The process of claim 29, wherein the product of step i) has a drug:ethylcellulose weight ratio (phase ratio) ranging between 1:1 and 30:1.

37. (Withdrawn) The process of claim 29, wherein the product of step i) has a drug:ethylcellulose weight ratio (phase ratio) ranging between 3:1 and 15:1.

38. (Withdrawn) The process of claim 29, wherein the microcapsules obtained in step ii) have a weight median diameter ranging between 20 μm and 800 μm and a drug potency ranging between 400 mg/g and 950 mg/g.

39. (Withdrawn) The process of claim 29, wherein the microcapsules obtained in step ii) have a

weight median diameter ranging between 100 µm and 400 µm and a drug potency ranging between 400 mg/g and 950 mg/g.

40. (Previously presented) The composition of claim 15, wherein said acrylic polymer is soluble in 1N HCl.

41. (Previously presented) The composition of claim 15, wherein said acrylic polymer is Eudragit E.

42. (New) A composition comprising microcapsules comprising:
a. drug microparticles;
b. a first layer disposed over said microparticles, consisting essentially of ethylcellulose; and
c. a second layer disposed over said first layer, consisting essentially of an acrylic polymer,
wherein said acrylic polymer is soluble in the stomach.